

REMARKS

A. Status of Claims

Claims 1 to 4, 6 to 9, 14 to 31, 33 to 37, 39 and 40 are now pending. Claim 32 has been cancelled. Claims 1, 3, 20 and 21 have been amended by virtue of the present Amendment.

It is respectfully submitted that no new matter was added in this amendment.

B. Specification

In the Office Action, the Examiner objected to the Specification because it is missing a section entitled: "Cross-References to Related Applications".

In response, a section entitled Cross References to Related Applications has been added to the Specification.

In the Office Action, the Examiner also objected to the Specification because it is missing a section entitled: "Brief Summary of the Several Drawings".

In response, Applicants point out that a heading entitled "BRIEF DESCRIPTION OF THE DRAWINGS" was added to the Specification in Applicant's October 7, 2005 Preliminary Amendment. Applicants have amended its description of drawings for Figures 8A and 8B and Figures 8C to 8G and 8AA. Applicants have also added descriptions for Figures 12 to 66 to page 20 of the Specification, after line 2.

The description of the Figures can be found throughout the Specification as filed. It is therefore submitted that no new matter has been added to the application.

In the Office Action, the Examiner also alleged that the title of the invention is not descriptive and requested amendment to a Title that is clearly indicative of the invention to which the claims are directed. In response, the Title has been amended to "PASSIVE DRY POWDER INHALER DEVICE CONTAINING APOMORPHINE AND METAL STEARATE FORMULATION".

C. Claims

The Examiner objected to Claim 20 and requested correction to insert the words "is reached" in line 1 of claim 20 between the words "level" and "within". This amendment has been made.

D. Rejection under § 112

Claims 1-4, 6-9, 14-37, and 39-40 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserted Claim 1 was confusing because it states that the dry powder "comprises" a dry powder formulation and noted that the specification states that the dry powder inhalers "contain" a dry powder formulation. Claim 1 has been amended to change the term "comprising" to the term "containing".

The Examiner rejected Claim 3 as vague and indefinite, asserting that it is unclear whether a dosing at 2 microns of at least 40% is a required limitation due to the presence of the term "preferably" in the claim. In response, the term "preferably" has been deleted.

The Examiner rejected claim 6 as being vague and indefinite, asserting that on line 2 it utilizes "means + function" language, and thus invokes provisions of 35 U.S.C. § 112, 6th paragraph. In response, Applicants point to pages 87 to 89 of the PCT publication which provide sufficient explanation of the means that can be used to produce droplets moving at a controlled velocity and of a predetermined size. For example, page 89 states "Preferably, the means for producing droplets moving at a controlled velocity and of a predetermined-size is an alternative to the commonly used 2-fluid nozzle. In one embodiment, an ultrasonic nebuliser (USN) is used to form the droplets in the spray drying process." Figures 41 and 42 also show a schematic diagram of an ultrasonic nebuliser producing fine droplets and a spray drier incorporating an ultrasonic nebuliser. Moreover, claim 7 specifically mentions an ultrasonic nebuliser. As a result, the means plus function language employed in claim 6 is adequately supported.

The Examiner rejected claim 9 as being vague and indefinite, claiming that it is unclear how the method of the recited product-by-process limitation is utilized. In response, Applicants point out that jet milling of apomorphine particles in the presence of metal stearate is described in detail in the accompanying description on pages 116 to 118 of the PCT publication.

The Examiner rejected Claim 21, claiming the phrase “the pharmacodynamic effect” in line 2 lacked antecedent basis. In response, this phrase has been amended to “a pharmacodynamic effect”.

The Examiner rejected Claim 32 as vague and indefinite, asserting the phrase “adverse side effects normally associated with administration of apomorphine via other routes” is ambiguous. Claim 32 has been cancelled, rendering this objection moot.

In view of the above, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph rejections.

E. Rejection under § 103(a)

Claims 1-4, 9, 14-37 and 39-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Staniforth et al. (US 2004/0204439). The present application, U.S. Serial No. 10/552326, is a national phase application of PCT/GB2004/001628, filed on 14 April 2004, which claims priority to U.S. Serial No. 10/413022, U.S. Serial No. 10/621964 and GB0321612.4, as can be seen from the PCT pamphlet and other application documents before the USPTO. The cited Staniforth reference, U.S. Publication No. 2004/0204439, is the publication of U.S. Serial No. 10/413022. Therefore, this priority document cannot be cited against the current application.

Applicants respectfully request withdrawal of this rejection based on its claim of priority.

F. Non Statutory Double Patenting

Claims 1-4 and 19-32 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 21, 24, 26, 42 and 44 of copending Application No. 10/552,231 and also over claims 1 and 99-100 of copending Application No. 12/459,686 in view of Staniforth et al. (US 2004/0204439).

In response, Applicants submit that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

Conclusion

This Response is being submitted in response to the Office Action dated March 12, 2010 in the above-identified application. Concurrently with this Response, Applicant submits a petition for a one-month extension of time for filing a response, along with the requisite fee. Therefore the time for filing a response to the March 12, 2010 Office Action is thereby extended to July 12, 2010, and this Response is being timely filed. If it is determined that any additional fee is due in connection with this filing, the Commissioner is authorized to charge said fees to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly requested.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: /Leslye Davidson/
Leslye Davidson, Reg. No. 38,854

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940